NOV 0 8 2001

K010819

This summary regarding 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1) Date of Summary: 14 Mar 2001

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2)
Device Name: 1cc/ml NMT Safety Syringe
Common Name: Piston Syringe
Classification: Class II Medical Device
3)
Substantailly Equivalent Device: 3cc NMT Safety Syringe
510(k) Number: K982431
4)

General

The NMT Safety Syringe is a standard piston syringe with integral needle. The syringe incorporates automatic retraction technology that enables contaminated needles to be withdrawn, safely away inside the body of the syringe when the syringe plunger is fully depressed.

To ensure that the safety and effectiveness of the device is maintained at the highest levels, a series of voluntary standards have been referenced during the design of the product and processes used for the NMT Safety Syringe.

- ISO 6009:1992(E), Hypodermic needles for single use - Colour coding for identification.
- ISO 7864:1993(E), Sterile hypodermic needles for single use.
- ISO 7886-1:1997(E), Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.
- ISO 9626:1991(E), Stainless steel needle tubing for manufacture of medical devices.
- ISO8537:1995, Sterile, single-use syringes, with or without needle, for insulin.

- Guideline On Validation Of The Limulus Amebocyte Lysate (LAL) Test As An End-Product Endotoxin Test For Human And Animal Parenteral Drugs, Biological Products And Medical Devices, Food And Drug Administration.
  ANSI/AAMI/ISO 11137, Sterilisation of health care products – Requirements for validation and routine control – Radiation sterilisation.
- ISO10993 Part 1 – Biological Evaluation of Medical Devices – Guidance on Selection of Tests.

Reference has also been made to guidance documents provide by CDRH relating to piston syringes and devices incorporating sharps injury prevention features.

- "Guidance On The Content Of Premarket Notification [510(K)] Submissions For Piston Syringes" and;

- "Supplementary Guidance On The Content Of Premarket Notification [510(K)] Submissions For Medical Devices With Sharps Injury Prevention Features".

The NMT Safety Syringe performance specification conforms to all performance criteria derived from the above voluntary standards and guidance documents. As the device is designed, with reference to voluntary standards, to be used as a standard piston syringe there is no effect on the safety and effectiveness of the device.

5)
The NMT Safety Syringe is intended for use as a standard piston syringe with integral needle. This also incorporates automated needle retraction technology. The following indications for use are made for the NMT Safety Syringe:

The function of the NMT Safety Syringe is to provide a safe and reliable method of injecting medication into a patient that also protects the user from potential needlesticks.
The NMT Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retraction mechanism. Because the contaminated needle is automatically withdrawn into the syringe barrel, the syringe user is protected from accidental needlesticks. These accidental needlesticks would occur between removing the needle from the patient and disposing of the syringe in a sharps disposable container.

The NMT Safety Syringe is not to be used with paraldehyde.

6)
The 1cc/ml NMT Safety Syringe is substantially equivalent to the previously marketed 3cc/ml NMT Safety syringe. Technologically, both devices are standard piston syringes which utilise springs to retract the needle when the plunger is fully depressed. Both devices are designed for one-handed operation and have the same indicated use.
Bench testing has been conducted to examine the key operations associate with the use of both devices. This has included evaluation of the dead space in the device, the graduated capacity, the forces involved with the operation of the retraction mechanism and the pressure rating of the devices under worst case static loading. In all cases the 1cc/ml NMT Safety Syringe was either equivalent to the performance of the 3cc/ml NMT Safety syringe.

7)
Biological evaluation of the materials incorporated in the NMT Safety Syringe has been conducted according to voluntary standards referenced. The sterilisation of the device by Gamma irradiation has also been validated to and SAL of 10^{-6}.

In summary, the 1cc/ml NMT Safety Syringe has been proven to be a safe and effective device whose design is appropriate for its indicated use. The 1cc/ml NMT Safety Syringe is equivalent to the previously marketed device, the 3cc NMT Safety syringe. Both of these devices are suitable for subcutaneous, intramuscular and intravenous use.

Mark Marosz

Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV 0 8 2001

New Medical Technology Limited
Mr. Mike Malandrakis
New Medical Technology Incorporated
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P.O. Box 317
Zionsville, Indiana 46077

Re: K010819
Trade/Device Name: 3CC Safety Syringe
Regulation Number: 880.5860
Regulation Name: Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: August 28, 2001
Received: August 31, 2001

Dear Mr. Malandrakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications For Use Statement

510(k) Number (if known): K010819.

Trade Name: NMT Safety Syringe.

Indications For Use:

The function of the NMT Safety Syringe is to provide a safe and reliable method of injecting medication into a patient that also aids in the prevention of accidental needlestick injuries.

The NMT Safety Syringe functions the same as a standard hypodermic syringe except for its ability to retract the contaminated needle inside the syringe barrel immediately after the completion of the injection, aiding in the prevention of accidental needlesticks. Needlestick injuries might otherwise occur when removing the needle from the patient and disposing of the syringe into a sharps disposable container.

Prescription Device: The NMT Safety Syringe for subcutaneous, intramuscular, tuberculin and intravenous (IV) use in both 1 ml/cc and 3 ml/cc sizes are prescription devices and are labeled appropriately. The insulin syringe (1 ml/cc) is a non-prescription device and does not have the prescription statement.

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K010819